American Red Cross National Headquarters

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Date: October 12, 2000

From: Anita T. Ducca
Director, Regulatory Relations
American Red Cross

To: Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane RM 1061
Rockville, MD 20857

Re: Participation in the PDMA Public Hearing (Docket Number 92N-0297)

On behalf of the American Red Cross (ARC), this is to request a place on the agenda for an ARC representative to speak at the upcoming Public Hearing scheduled for October 27 on the Prescription Drug Marketing Act of 1987 (Docket Number 92N-0297; FDA-PDMA Hearing). The information pertaining to ARC's request is as follows:

Name and Title of Speaker: Chris Lamb, Vice President, Plasma Services
Address: American Red Cross
1616 North Fort Myer Drive, Arlington, VA 22209
Telephone: 703-312-8701
Affiliation: American Red Cross
Length of time requested: 10 Minutes
Statement Summary: Please see attachment

If you have any questions please contact me at 703-312-5601. Thank you.

92N-0297 APE 7

Summary of the
Statement by the American Red Cross
at the
Public Meeting on the Prescription Drug Marketing Act of 1987
Docket Number 92N-0297; FDA-PDMA Hearing
October 27, 2000

The American Red Cross (ARC), which provides nearly half the nation's blood supply, will describe its blood collection, processing, and distribution system. Emphasis will be placed on the recovery of plasma that is fractionated into derivative products distributed under the ARC label to hospitals, hemophilia treatment centers, and other providers. Changes in the distribution system used by ARC in order to implement the regulation and potential impacts on the availability of the plasma derivative supply as well as on the health care centers and patients we currently serve, will be covered. Finally, ARC will address the *"Questions on Distribution of Blood Derivatives by Blood Banks and Other Health Care Entities"* listed in the Federal Register notice of September 19 announcing the public meeting.